

REMARKS

The finality of the Restriction Requirement has been noted.

Claim 4 has been canceled and the objection to claim 4 has been rendered moot.

Claims 1-3, 5, 12-15 and 21-26 were rejected under 35 U.S.C. §102(b) as being anticipated by Shah et al. (Shah).

Reconsideration is requested.

Shah was applied as teaching divisible tablets for facilitating fractional dosing of medication where the sustained release characteristics were retained by each fractional dose. Claim 1 has been amended by combining claim 1 with the substance of canceled claim 4. Nothing in the Shah patent discloses the concept of providing a segment in a divisible table where the first segment has either an undetectable amount of a drug, a pharmacologically ineffective amount of a drug or a pharmacologically effective amount of a drug or drugs that are present in the second segment. For these reasons, it is requested that the rejection for lack of novelty be withdrawn.

Claims 4, 6-11, 16-17 and 33 were rejected under 35 U.S.C. §103(a) as being unpatentable over Shah in view of Conte et al. (Conte).

Reconsideration is requested.

As noted above, the Shah patent does not disclose the concept of providing a segment in a divisible table where the first segment has either an undetectable amount of a drug, a pharmacologically ineffective amount of a drug or a pharmacologically effective amount of a drug or drugs that are present in the second segment. The Conte patent has been cited as disclosing a multilayer tablet where the first layer contains one or more drugs with an immediate or a controlled release formulation. The second layer contains a drug with a slow release formulation and a third layer which has a low

permeability barrier coating. The Examiner concluded that it would be obvious to one of ordinary skill in the art to make divisible tablets where the sustained release characteristics are retained as taught by Shah and to combine that tablet with the tablet disclosed by Conte.

The amended claims point out a tablet having a first unitary segment one face of which is contiguous with a second unitary segment that contains a drug or drugs, where said first segment contains either an undetectable amount of a drug, a pharmacologically ineffective amount of drug, or a pharmacologically effective quantity of said drug or drugs present in said second segment, but has fewer milligrams of said drug or drugs relative to the excipients in each segment than does said second segment. The Conte patent requires that the first and second contiguous segments must both contain drugs and that the third non-contiguous segment be the segment that has no drug. If one were to make the tablet defined by the amended claims of the present application, the teachings of Conte would have to be disregarded as Conte explicitly requires that the only tablet that he discloses must have two contiguous active layers. It is not obvious to make a tablet that has a structure which can only be made by ignoring the teachings of the prior art.

Even when Conte is combined with Shah, there is no reason to modify Conte and have only one active segment contiguous with an inactive segment.

A pharmaceutical tablet as defined in claim [[4]] 1 in which the first segment contains no more than 10 parts per million of the concentration of the drug or drugs present in said first unitary segment and said second unitary segment.

Claim 8 points out a tablet in which the first segment contains no more than 10% of the concentration of drug or drugs present in the first unitary segment and said second unitary segment. This is not suggested by either the Shah or Conte patents when considered alone or in combination.

Claim 9 points out a tablet in which the first segment

contains no more than a 2% concentration of the drug that is present in the first unitary segment and said second unitary segment. This is not suggested by either the Shah or Conte patents when considered alone or in combination.

Claim 10 points out a tablet as defined in which the first segment is derived from a granulation that does not contain a drug. This is not suggested by either the Shah or Conte patents when considered alone or in combination.

Claim 15 points out an embodiment having a vertical score aligned with the center of the space between said first unitary segment and said second unitary segment. This structure is not made obvious by the Shah or Conte patents.

Claims 17-18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Shah in view of Addicks et al. (Addicks).

Reconsideration is requested.

Claims 17-18 are directly or indirectly dependent on amended claim 1. The Shah patent has been distinguished from amended claim 1 above and nothing in Addicks discloses the invention as defined by amended claim 1 which requires that a specific first segment be contiguous with the defined second segment of the tablet. Addicks is concerned with a multilayer tablets that comprises warfarin. For these reasons, it is requested that this ground of rejection be withdrawn.

Claims 17 and 19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Shah in view of Eberlin et al. (Eberlin).

Reconsideration is requested.

The Shah patent has been distinguished from amended claim 1 above and nothing in Eberlin discloses the invention as defined by amended claim 1 which requires a specific first segment to be contiguous with the defined second segment of the tablet. Eberlin is concerned with a tablet that comprises digoxin. For these reasons, it is requested that this ground of rejection be withdrawn.

Claims 17 and 20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Shah in view of Franz et al. (Franz).

Reconsideration is requested.

The Shah patent has been distinguished from amended claim 1 above and nothing in Franz discloses the invention as defined by amended claim 1 which requires a specific first segment to be contiguous with the defined second segment of the tablet. Franz is only concerned with a tablet that comprises levothyroxine sodium. For these reasons, it is requested that this ground of rejection be withdrawn.

Claims 1-26 and 33 have been provisionally rejected for double patenting over Serial No. 11/441,455 and have also been rejected over U.S. 7,329,418 and U.S. 7,318,935 for double patenting.

The provisional rejection of claims 1-26 and 33 for double patenting has been noted since no claims have been allowed in either application, no action is required at this time.

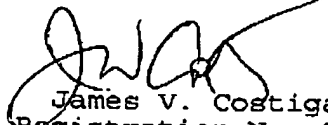
The claims of U.S. 7,329,418 (the '418 patent) do not make the claimed subject matter of the amended claims of the present application obvious because the claims of the '418 patent require a three layer structure and a particular height to width ratio. These structural elements do not make the claimed tablet obvious. This is particularly evident for claim 18, 19 and 20 which points out particular drugs that are not pointed out by the claims of the '418 patent.

The claims of U.S. 7,318,935 (the '935 patent) do not make the claimed subject matter of the amended claims of the present application obvious because the claims of the '935 patent also require a three layer structure and a particular height to width ratio. In addition, the subject matter of claims 18-20 of the present application are not made obvious by the claims of the '935 patent.

The applicants have disclosed a novel and unobvious invention and patent protection should be allowed.

An early and favorable action is earnestly solicited.

Respectfully submitted,


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